

FOI 23/184 – Sublocade application

REQUEST

10 March 2023

Would you please give an update with regards to Indivior's application to licence Sublocade or RBP-6000 (alternative name is sometimes Subutex Pro) for use in the UK and if these licences have been granted, if not, when are they likely to be granted? If they have been declined, what is the reason for declining the application?

MHRA RESPONSE

22 March 2023

Thank you for your request under the Freedom of Information Act (FOIA).

There is no authorised product called “Sublocade”, “RBP-6000” or “Subutex Pro”.

Unfortunately, the Medicines and Healthcare Products Regulatory Agency cannot provide information on whether an application for Sublocade, RBP-6000 or Subutex Pro has been submitted. We refuse to confirm or deny that we hold this information under Section 41 (S41 – information provided in confidence) and Section 43 (S43 – commercial interests) of the Freedom of Information Act (FOIA).

Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. Section 43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in publishing this information, which would alert competitors to whether a product is close to being marketed in the UK or not.

There are Clinical Trial databases available where records of clinical trials that are currently in progress, as well as completed trials, can be searched:

<https://www.clinicaltrialsregister.eu/ctr-search/search>

<https://www.isrctn.com/>

There are also other Subutex products that are marketed in the UK. Further information is available through the MHRA Product Portal, please see link below:

<https://products.mhra.gov.uk/search/?search=Subutex&page=1>

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
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